Attachment 14: Consent Statement for CLIC Study

The NIH-AARP Diet and Health Study Evaluation of Computerized Health and Lifestyle Questionnaires

Consent Form

Full Study Title: *The NIH-AARP Diet and Health Study Evaluation of Computerized Health and Lifestyle Questionnaires* [tentative]

Conducted by: United States National Cancer Institute, Division of Cancer Epidemiology and Genetics, Nutritional Epidemiology Branch

Principal Investigator: Arthur Schatzkin, M.D., Dr. PH

Funded by: United States National Cancer Institute

Why is this study being done?

The purpose of the *NIH-AARP Diet and Health Study Evaluation of Computerized Health and Lifestyle Questionnaires* is to collect information about diet, health, and lifestyle factors using computerized questionnaires. This study adds onto the NIH-AARP Diet and Health Study that began in 1995 and has approximately 500,000 persons still participating in follow-up. The original NIH-AARP Diet and Health Study collects information on diet and health using paper-based questionnaires sent in the mail. Answers from the questionnaires are combined with information on cancer and death in participants that comes from state and national statistics. As a result, researchers have learned more about how health behaviors are related to cancer and other diseases and over 30 articles have published in scientific journals.

This new study will invite 5,000 current participants in the NIH-AARP Diet and Health Study and 10,000 newly invited persons who are AARP members age 50 and over. The *NIH-AARP Diet and Health Study Evaluation of Computerized Health and Lifestyle Questionnaires* will evaluate how much participation there is in this type of study and if participants complete the computerized questionnaires they are asked to do at different times over a few months. The study will also assess participant responses about diet, daily activities, and overall health and lifestyle. Information from this study will help researchers determine the best ways to use computerized questionnaires for research on diet and health.

What does it mean to participate?

If you are willing to participate, you will be asked a few initial questions about who you are and some identifying information such as your address, telephone number, email address, and sometimes social security number. Your answers are confidential and securely encrypted so that no access to this information is possible except for study purposes. Identifying information is separated from your responses so that your questionnaire responses cannot be linked to you.

Once you agree to participate, you will be linked to a separate secure internet site where you will create your own username and password in order to begin the questionnaires. Each time you are scheduled to complete a new set of questionnaires, you will be sent an email message from the study at xxxxxxx@xxxx.gov. For each set of questionnaires, participants may be asked to complete information about foods they've eaten the day before, their daily activities the day before, a lifestyle and health

history survey, and/or a dietary questionnaire about foods eaten over the past year. Exactly how long it takes you to complete the questionnaires will depend on the questionnaires you are asked to do at that time and the answers you give in the questionnaires. We estimate that it will take 20 minutes to 1 hour each time you are asked to complete a set of questionnaires.

How long is this study?

Most participants will be asked to complete computerized questionnaires at the beginning of the study and two months later. Some participants will also be asked to complete a questionnaire one month after they start the study and then again, at two months and three months after they start the study (four times altogether). Participants selected to participate in the study are being asked to complete questionnaires at different time periods in order to see the best pattern for completing questionnaires. The *NIH-AARP Diet and Health Study Evaluation of Computerized Health and Lifestyle Questionnaires* will end in seven months, but most participants will be finished with all questionnaires in less than four months.

What are the risks and benefits of participating in this study?

Your participation in this research study is completely voluntary. This research project involves no more than minimal risk and does not affect your health care benefits or any other benefits you may receive.

There are no direct benefits to you for participating in this study. The information you provide may benefit society by increasing researchers understanding of how to best collect information for research on the role of diet, daily activities, and health and lifestyle factors.

Will the information I give be kept confidential?

The personal information you provide in this study will be kept confidential and secure. All personal identifying information will be securely encrypted and stored separately from the responses you give on the study questionnaires. Personal identifying information will be stored in a secure, password protected, and locked data file and only identified by a study number. In order to protect the confidentiality of the information you give us, only a study number will be used to identify you and the information you provide.

The study staff is required to keep your identity confidential and your name will never be used in any publications or presentations about this study. All staff working on the study will be required to sign a statement pledging to maintain the confidentiality of all data. Access to study data will be limited to the staff working on the study. When the study is complete or until the data is no longer required for research, the data will be archived and/or destroyed.

What else do I need to know about the study?

Your participation in this study is completely voluntary. If you decide to participate, you may decide not to answer specific questions or leave the study at any time. The study investigators will use the information collected from you during the study up until the time you leave the study. There will be no penalty or loss of benefits to you if you decline to participate in the study or if you decide to leave the study at any time.

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What if I have questions, comments, or concerns?

This consent form explains the research study. If you have any questions, comments, or concerns about the study or the informed consent process, you may telephone (301) 594-2931 or email the Principal Investigator, Arthur Schatzkin, M.D., Dr. P.H. at schatzka@mail.nih.gov .

If you have any questions about your rights as a research participant, you may contact _____ at the National Cancer Institute Special Studies Institutional Review Board.

Approvals

This study protocol and this informed consent form have been reviewed by the institutional review boards of the U.S. National Cancer Institute and other organizations participating in monitoring the research data. These review committees monitor the safety and the rights of individuals participating in this research study.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

☐ I have read this informed consent information and agree to participate in the study.

☐ I have read the informed consent information above and do not want to participate in the study.